

REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

Summary

As is correctly noted in the Office Action Summary, Claims 16-34 are pending. Claims 16, 17, 28-31, and 34 have been withdrawn from consideration. Claims 18-27, 32, and 33 stand rejected. Acknowledgment has been made to a claim for foreign priority under 35 U.S.C. § 119 (a-d) or (f). Certified copies of the priority documents are being filed concurrent with the instant Reply. Acknowledgment of receipt of these documents is respectfully requested.

Amendments

By the foregoing amendments, Applicants have canceled non-elected Claims 16, 17, 28-31, and 34, without prejudice or disclaimer. Applicants reserve the right to file one or more applications directed to the previously-presented subject matter.

Also by the foregoing amendments, Claims 18-21 have been amended to better define Applicants' invention and to delete dependency on non-elected claims. No new matter has been added.

By the foregoing Amendments, Applicants have replaced the Abstract.

Finally, by the foregoing amendments, Applicants have amended the "Brief Description of the Drawings" in the Specification to reference subparts of the Figures and SEQ ID NOs., as requested by the Examiner. Applicants have *not* amended Page 7, Lines 18-19, and 23, to include SEQ ID NOs, because the sequences found at those locations are merely primers, are not part of Applicants' invention, and are not claimed.

Rejections Under 35 U.S.C. § 101

Turning now to the Official Action, Claims 18-21 have been rejected under 35 U.S.C. § 101 as purportedly drawn to non-statutory subject matter. *See Page 4, ¶ 7, of the Official Action.* According to the Examiner, the claimed genes may be found in nature and are, therefore, unpatentable. *Id.*

By the foregoing amendments, Claims 18-21 have been amended to specify that the claimed genes are "isolated." Applicants believe the amendments to Claims 18-21 have rendered the Examiner's rejections moot. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 101 rejections against Claims 18-21.

Rejections Under 35 U.S.C. § 112

Claims 20-27, 32, and 33 have been rejected under 35 U.S.C. § 112, second paragraph, as purportedly indefinite. *See Page 5, ¶ 8, of the Official Action.*

Claims 20 and 21 have been amended to specify that referenced nucleotides 1-1298 are found in SEQ ID NO: 2. Applicants believe these amendments have removed any potential confusion as to which sequence/sequence listing is referenced.

Claims 20 and 21 have also been amended such that the language previously considered indefinite ("stringent conditions" and "homology") has been removed.

Based on the foregoing, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph, rejections against Claims 20-27, 32, and 33.

Claims 18-21, 32, and 33 have been rejected under 35 U.S.C. § 112, first paragraph, as purportedly lacking sufficient written description. *See pages 5-8, ¶ 9, of the Official Action.* These rejections are respectfully traversed.

Claims 18 and 20 have been amended to claim isolated genes defined by SEQ ID NOs. 1 and 2, respectively. Applicants believe that the amendments to Claims 18 and 20 have rendered moot the Examiner's alleged lack of written description rejections.

Claims 19 and 21 have been amended to specify that the claimed isolated genes are defined by having at least 90% identity with SEQ ID NOs. 1 and 2 and by having the activity to biosynthesize theobromine using 7-methylxanthine as the substrate.

As noted by the Examiner, the sequence of clone #45 is shown in SEQ ID NO: 2, which encodes the amino acid sequence of SEQ ID NO: 1. *See Official Action, Page 7.* The Specification teaches that genes whose base sequences have 10 or less (preferably 7 or less or 3 or less) deletions, substitutions, or additions to the base sequence of

SEQ ID NO: 2; exhibit 90% or more homology/identity (preferably 95% or more or 99% or more) to the base sequence of SEQ ID NO: 2; and encode a polypeptide that catalyzes biosynthesis of theobromine using 7-methylxanthine as the substrate are part of the invention. *See, e.g., Page 4, ¶ 0011, Lines 21-33 of the Specification.*

One skilled in the art, armed with SEQ ID NOs: 1 and 2 and the knowledge that Applicants' Specification states that sequences:

- (1) with 10 or less deletions, substitutions, or deletions;
- (2) with homology/identity of 90% or more; and
- (3) encoding a polypeptide having activity of catalyzing biosynthesis of theobromine

using 7-methylxanthine as the substrate

are within Applicants' invention would reasonably conclude that Applicants had possession of the claimed invention. Applicants' Specification and originally-filed claims evince possession of the claimed invention, as the invention is described with its limitations in terms that fully set forth the invention. *See Lockwood v. American Airlines*, 107 F.3d 1565, 1572 (Fed. Cir. 1997); *M.P.E.P.* § 2162.

Accordingly, Applicants maintain that Claims 18-21, 32, and 33 are sufficiently described, and respectfully request withdrawal of the 35 U.S.C. § 112, first paragraph, rejections.

Claims 18-27, 32, and 33 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled. *See Pages 8-11, ¶ 10, of the Official Action.* These rejections are respectfully traversed.

The enablement component of 35 U.S.C. § 112, first paragraph, is a separate requirement from the written description requirement. *See Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). To satisfy the enablement requirement, the Specification must describe how to make and use the invention. *See M.P.E.P. § 2164.* The enablement requirement may be phrased as: Is the experimentation needed to practice the invention undue or unreasonable? *See In re Wands*, 858 F.2d 731,737 (Fed. Cir. 1988). Applicants maintain that the Specification instructs one how to make and use the claimed invention and that one of skill in the art can readily practice the claimed invention without undue or unreasonable experimentation.

As discussed above, and as recognized by the Examiner, the Specification provides the nucleic acid and amino acid sequences that encode products having N-methyltransferase activity. *See, e.g., ¶¶ 0004, 0005, 0011, and 0012 of the Specification; Official Action, Page 7.* The Specification further provides that one: may delete, add, or substitute no more than 10 bases from SEQ ID NO: 2, must have 90% homology/identity or more to SEQ ID NO: 2, and must have activity of catalyzing biosynthesis of theobromine using 7-methylxanthine as the substrate. One of skill in the art could readily practice the invention by modifying SEQ ID NO: 2, based on the detailed parameters provided. Accordingly, the experimentation needed to practice the invention is neither undue nor unreasonable.

With respect to Claims 22 and 32, which claim a transformed plant with decreased expression and a method for producing such a plant, Applicants maintain that one skilled in the art could readily utilize any art-recognized technique for inhibiting expression, and need not use only the techniques listed in the Specification. The techniques provided in the Specification, *see, e.g., those in ¶¶ 0014-0015*, are merely examples of art-recognized techniques.

Based on the foregoing, Applicants maintain that one of skill could readily make and use the claimed invention, using Applicants' disclosure. Given the detailed information provided in the Specification, one of skill need not conduct undue or unreasonable experimentation to arrive at Applicants' invention. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, first paragraph, enablement rejections of Claims 18-27, 32 and 33.

Rejections Under 35 U.S.C. § 102

Claims 18-21 have been rejected under 35 U.S.C. § 102(a) as allegedly anticipated by Ogawa et al., 276 J. BIOL. CHEM. 8213-8218 (Mar. 16, 2001) ("Ogawa"). *See Pages 11-12, ¶ 11, of the Official Action.*

As noted by the Examiner, Applicants have claimed foreign priority to Japanese Patent Application No. 2000-307,149, filed on October 6, 2000. *See Official Action, Pages 3,7.* Concurrent with the filing of this Reply and Amendment, Applicants are filing a Claim for Convention Priority with a certified copy of the priority document. In

addition, attached to this Reply and Amendment is a Sworn English translation of the priority document.

Because Japanese Patent Application No. 2000-307,149 pre-dates Ogawa, Applicants believe the rejection of Claims 18-21 under 35 U.S.C. § 102(a) has been rendered moot, and respectfully request withdrawal of the rejection.

Claims 18, 20, 22, 23, 25, 32, and 33 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Mizuno *et al.*, EP1055727 A2 ("Mizuno"). *See pages 12-13, ¶ 12, of the Official Action.* This rejection is respectfully traversed.

To anticipate a claim, a single source must contain all elements of the claim. *Hybritech, Inc. v. Monoclonal Antibodies*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). Missing elements may not be supplied by the knowledge of one skill in the art or the disclosure of another reference. *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716 (Fed. Cir. 1984). Applicants maintain that Mizuno does not disclose all elements of Claims 18, 20, 23, 25, 32, and 33. Specifically, Mizuno does not disclose an isolated gene encoding a polypeptide consisting of: the amino acid sequence defined by amino acids 1-378 of SEQ ID NO: 1 (Claim 18), or the nucleotide sequence defined by nucleotides 1-1298 of SEQ ID NO: 2 (Claim 20). By extension, Mizuno does not disclose all elements of Claims 23; 25, 32, and 33, which depend on Claim 18 and/or 20.

Based on the foregoing, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(b) rejections of Claims 18, 20, 23, 25, 32, and 33, based on Mizuno.

Rejections Under 35 U.S.C. § 103

Claims 18-27, 32, and 33 have been rejected under 35 U.S.C. § 103(a) as purportedly obvious over Mizuno in combination with Hatanaka *et al.*, 19 PLANT CELL REP. 106-110 (1999) ("Hatanaka") and Ogawa. *See Pages 13-15, ¶ 13, of the Official Action.* This rejection is respectfully traversed.

When applying 35 U.S.C. § 103, four tenets of patent law must be adhered to: (1) the claimed invention must be considered as a whole, (2) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination, (3) the references must be viewed without the benefit of impermissible hindsight vision, and (4) a reasonable expectation of success is the standard with which obviousness is determined. *See MPEP § 2141*, citing *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 (Fed. Cir. 1986). Moreover, to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference or to combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art reference(s) must teach or suggest all of the claim limitations. *See MPEP § 2142*. Applicants respectfully assert that these tests of obviousness have not been met in this case.

According to the Examiner, Claims 18-27, 32, and 33 are obvious because one would have: (1) substituted N-methyltransferase gene of Mizuno with the CaMXMT gene of Ogawa; and (2) substituted the transformation method of Mizuno with the transformation method of Hatanaka. As discussed above, Ogawa is not a proper publication under 35

U.S.C. § 103(a), and should be removed from the rejection. Without Ogawa, the Examiner's proposed modifications to arrive at the claimed invention could not occur.

Because a *prima facie* case of obviousness has not been established, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejections against Claims 18-27, 32, and 33.

CONCLUSION

From the foregoing, further and favorable consideration in the form of a Notice of Allowance is respectfully requested and earnestly solicited.

In the event that there are any questions relating to this response, or the application in general, it would be greatly appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,
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Attachment to Reply and Amendment Dated January 24, 2003

Marked-up Copy

[0008] The present invention will be further explained in detail hereafter with reference to the accompanying drawings, in which:

Fig. 1 is a drawing showing the pathway of caffeine biosynthesis ;

Fig. 2 is a drawing showing base sequences of cDNAs obtained from MTL1, MTL2, MTL3 and MXMT1. Fig. 2A shows the base sequence of cDNA obtained on clone #1 (SEQ ID NO: 4). Fig. 2B shows the base sequence of cDNA obtained on clone #6 (SEQ ID NO: 6). Fig. 2C shows the base sequence of cDNA obtained on clone #35 (SEQ ID NO: 8). Fig. 2D shows the base sequence of cDNA obtained on clone #45 (SEQ ID NO: 2);

Fig. 3 is a drawing showing alignment of amino acid sequences obtained from MXMT1 (SEQ ID NO: 2), MTL1 (SEQ ID NO: 4), MTL2 (SEQ ID NO: 6) and MTL3 (SEQ ID NO: 8);

Fig. 4 is a photograph showing the results of SDS-PAGE analyses performed on fusion proteins obtained from MTL2, MTL3 and MXMT1;

Fig. 5 is a photograph showing the results of TLC to analyze enzymatic activities of the fusion proteins obtained from MTL2, MTL3 and MXMT1; and

Fig. 6A-6E shows [is a chart showing the] results of HPLC performed to identify reaction products in the enzymatic reaction mixture of the fusion protein obtained from MXMT1 identified by HPLC.



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Marked-up Claims 18-21

18. (Once Amended) [A] An isolated gene encoding [the] a polypeptide
[according to claim '16] consisting of the amino acid sequence defined by amino acids 1-378
of SEQ ID NO: 1.
19. (Once Amended) [A] An isolated gene encoding [the] a polypeptide [claim
17] consisting of an amino acid sequence exhibiting at least 90% identity with the amino
acid sequence defined by amino acids 1-378 of SEQ ID NO: 1, wherein said polypeptide
has the activity to biosynthesize theobromine using 7-methylxanthine as the substrate.
20. (Once Amended) [A] An isolated gene consisting of the nucleotide sequence
defined by nucleotides 1-1298 of SEQ ID NO: 2 [a base sequence of following (c), (d) or
(e):
(c) a base sequence defined by base numbers from 1 to 1298 shown in SEQ ID NO:
2 in a Sequence List,
(d) a base sequence in which a part of base sequence (c) is deleted or another base
sequence is added to said base sequence (c) or a part of base sequence (c) is substituted with
another base sequence, the base sequence (d) encoding a polypeptide having the activity to
biosynthesize theobromine using 7-methylxanthine as the substrate,

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Marked-up Claims 18-21

(e) a base sequence that hybridizes with said base sequence (c) under stringent condition, the base sequence (e) encoding a polypeptide having the activity to biosynthesize theobromine using 7-methylxanthine as the substrate].

21. (Once Amended) [A] An isolated gene consisting of a nucleotide sequence exhibiting at least 90% identity with the nucleotide sequence defined by nucleotides 1-1298 of SEQ ID NO: 2, wherein said isolated gene encodes a polypeptide having the activity to biosynthesize theobromine using 7-methylxanthine as the substrate [base sequence exhibiting at least 90% of homology with a base sequence defined by base numbers from 1 to 1298 shown in SEQ ID NO: 2 in a Sequence List].